

Message

From: Wozniak, Chris [wozniak.chris@epa.gov]
Sent: 1/17/2017 3:07:22 PM
To: Kough, John [Kough.John@epa.gov]
Subject: Intrexon/Oxitec Meeting
Attachments: removed.txt; Oxitec Pre-EUA Slides.pdf; Oxitec Pre-EUA Outline.pdf

FYI – have not looked at this yet; Laura just sent along.....

From: Epstein, Laura [mailto:Laura.Epstein@fda.hhs.gov]
Sent: Tuesday, January 17, 2017 10:02 AM
To: Wozniak, Chris <wozniak.chris@epa.gov>; Milewski, Elizabeth <Milewski.Elizabeth@epa.gov>
Subject: FW: Intrexon/Oxitec Meeting

FYI:

From: Sadove, Elizabeth
Sent: Tuesday, January 17, 2017 8:21 AM
To: Borio, Luciana; Mair, Michael; Epstein, Laura; Beers, Donald; Zborowsky, Ashley; Dass, Brinda; Nalubola, Ritu; Flamm, Eric; Maher, Carmen; Ross, Jennifer
Subject: FW: Intrexon/Oxitec Meeting

Please see message and attached from Intrexon....

From: McConagha, William [mailto:wmccconagha@sidley.com]
Sent: Monday, January 16, 2017 8:10 PM
To: Sadove, Elizabeth
Cc: Kulkarni, Deepti A.; McConagha, William
Subject: Intrexon/Oxitec Meeting

Hi, Liz.

On behalf of Intrexon/Oxitec, I write to submit materials in advance of the pre-submission meeting scheduled for Thursday the 19th at 1pm.

Attached please find the slide deck we propose to present at the meeting as well as a pre-EUA submission outline based on FDA guidance for EUA submissions and the regulation of GE animals. The pre-EUA submission draws heavily on data and information previously submitted to FDA and explains how Oxitec OX513A meets the EUA standard, as described in relevant law. 21 U.S.C. § 360bbb-3, as amended by Pub. L. 114-255, § 3088 (2016).

Please let us know if you have any questions or concerns.

I look forward to seeing you Thursday.

Best regards,

-Bill

WILLIAM A. MCCONAGHA
Partner

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